

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
17 May 2001 (17.05.01)

Applicant's or agent's file reference
P-4615.70

Applicant
BUSH, Charles, L., Jr. et al

- 1. The designated Office is hereby notified of its election made:**

in the demand filed with the International Preliminary Examining Authority on:

26 February 2001 (26.02.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>Olivia TEFY</p> <p>Telephone No.: (41-22) 338.83.38</p>
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INTERNATIONAL SEARCH REPORT

International application No. PCT/US00/20938

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/00

US CL : 604/181

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/181

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,921,966 A (BENDEK et al) 13 July 1999, Fig. 5a.	1-3

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 OCTOBER 2000	Date of mailing of the international search report 23 OCT 2000
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer KEVIN C. SIRMONS
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noted
9/14/03
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

FIEDLER, Alan W.
TECTON, DICKINSON AND COMPANY
1 Becton Drive
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ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF DEMAND
TO THE INTERNATIONAL BUREAU OR TO THE
COMPETENT INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 59.3(a) and (f) and Administrative Instructions,
Section 601(b))

FAXED IN ADVANCE ON: 15.03.01

Date of mailing
(day/month/year)

20.03.01

Applicant's or agent's file reference P-4615-70	IMPORTANT NOTIFICATION
International application No. PCT/US 00/ 20938	International filing date (day/month/year) 31/07/2000
	Priority date (day/month/year) 05/08/1999
Applicant TECTON, DICKINSON AND COMPANY et al.	

1. This International Preliminary Examining Authority, which has received on the date indicated below a demand for international preliminary examination, is not competent for the international preliminary examination of the international application:

26/02/2001 (date of receipt)

2. The applicant is hereby notified that:

this Authority has transmitted the demand to the International Bureau which will transmit it, as the case may be, directly to the competent International Preliminary Examining Authority and inform the applicant accordingly, or invite the applicant to indicate the competent International Preliminary Examining Authority to which the demand should be transmitted.

this Authority has transmitted the demand directly to the competent International Preliminary Examining Authority which is: **IPEA/US**

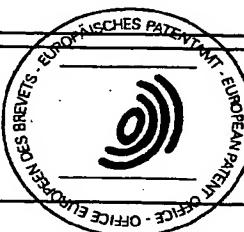
3. The date of receipt indicated above has been marked on the demand; the demand will, in accordance with Rule 59.3(e), be considered to have been received by the competent International Preliminary Examining Authority on that date of receipt.

ATTENTION: That date of receipt is AFTER the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices)(Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

(If applicable) The applicant has already been informed accordingly by telephone, facsimile transmission or in person, on:

4. A copy of this notification is being sent to the International Bureau or to the competent International Preliminary Examining Authority indicated above, as the case may be.

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer MORAN S A Tel. (+49-89) 2399-8123
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(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
15 February 2001 (15.02.2001)

PCT

(10) International Publication Number
WO 01/10484 A1(51) International Patent Classification⁷: **A61M 5/00**

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(21) International Application Number: **PCT/US00/20938**(74) Agents: **FIEDLER, Alan, W. et al.**; Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417 (US).

(22) International Filing Date: 31 July 2000 (31.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/147,330 5 August 1999 (05.08.1999) US(71) Applicant (for all designated States except US): **BECTON, DICKINSON AND COMPANY [US/US]**; 1 Becton Drive, Franklin Lakes, NJ 07417 (US).

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(81) Designated States (national): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

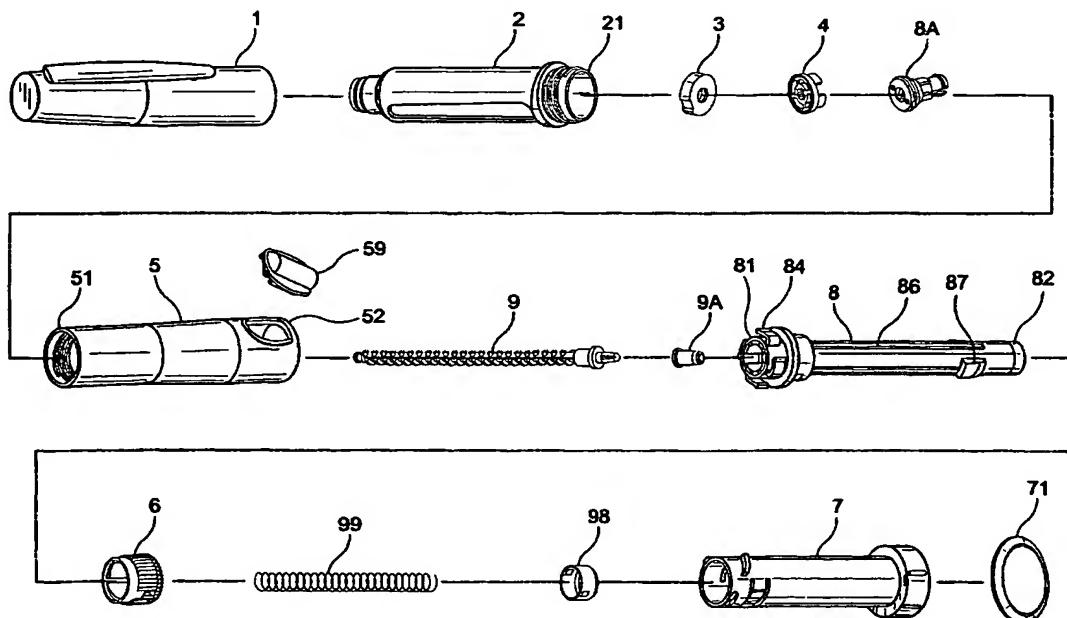
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

[Continued on next page]

(54) Title: MEDICATION DELIVERY PEN

**WO 01/10484 A1**

(57) Abstract: A medication delivery pen having a magnifier (59), a spring biased leadscrew (9) and an automatic release to allow the user to easily reset the dose on the medication delivery pen.

WO 01/10484 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

UNITED STATES PATENT APPLICATION

FOR: MEDICATION DELIVERY PEN

5

BACKGROUND OF THE INVENTION1. FIELD OF THE INVENTION

10 The present invention relates to a medication delivery pen having a variety of features and, more particularly, a medication delivery pen having a spring biased leadscrew to make priming easier and minimize underdosing and a magnifier for setting the dose.

15 2. DESCRIPTION OF RELATED ART

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel.

20 Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

25

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

20

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a cartridge holder into which a cartridge of insulin or other medication may be received. The cartridge holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art cartridge holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable cartridge for use

with the prior art cartridge holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art cartridge includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the cartridge. This prior art medication delivery pen is used
5 by inserting the cartridge of medication into the cartridge holder. A prior art pen body then is connected to the proximal end of the cartridge holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the cartridge distally for a distance corresponding to the selected dose.

10

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the cartridge holder such that the proximal point of the needle cannula pierces the elastomeric seal on the cartridge. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus
15 returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the cartridge will become exhausted after several such administrations of medication. The patient then separates the cartridge holder from the
20 pen body. The empty cartridge may then be removed and discarded. A new cartridge can be inserted into the cartridge holder, and the cartridge holder and pen body can be reassembled and used as explained above.

The above described medication delivery pen is effective and much more
25 convenient for self-administration of medication than the hypodermic syringes that use separate medication cartridges. However, the above-described medication delivery pen requires a number of parts which make the manufacture of these pens very expensive.

Hence, it is necessary to provide a medication delivery pen having a simple mechanism for setting the desired dose, simplifies loading of the cartridge, and makes priming easier to minimize underdosing.

5

SUMMARY OF THE INVENTION

The present invention relates to a medication delivery pen that addresses the above-identified problems and provides numerous features that have become expected by medication delivery pen users.

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The medication delivery pen according to the present invention includes a mechanism that automatically disengages the drive mechanism from the dose control mechanism to permit the user to reset the dose on the medication delivery pen.

15

Another feature of the present invention is an automatic mechanism that allows the user to easily load a new cartridge and automatically repositions the leadscrew next to the plunger when the cartridge holder is mounted on the body of the medication delivery pen.

20

Another feature of the present invention is a magnifier for easy viewing and setting of the desired dose.

BRIEF DESCRIPTION OF THE DRAWINGS

25

Fig. 1 is an exploded perspective view of a medication delivery pen according to the present invention.

Fig. 2 is a perspective view of the leadscrew in the medication delivery pen shown in Fig. 1.

Fig. 3 is a perspective view of the drive nut shown in Fig. 1.

5 Fig. 4 is a perspective view of the retract nut shown in Fig. 1.

Fig. 5 is a perspective view of the shuttle shown in Fig. 1.

10 Fig. 6 is a cross-sectional view of the body of the medication delivery pen shown in Fig. 1.

Fig. 7 is a perspective view of the dose knob of the medication delivery pen shown in Fig. 1.

15 Fig. 8 is a distal end view of the dose knob of the medication delivery pen shown in Fig. 1.

Fig. 9 is a cross-sectional view of the medication delivery pen shown in Fig. 1 fully assembled and in a dose setting condition.

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Fig. 10 is a cross-sectional view of the medication delivery pen shown in Fig. 9 in a dose set condition.

25 Fig. 11 is a cross-sectional view of the medication delivery pen shown in Fig. 9 in a reset dose condition.

Fig. 12 is an enlarged cross-sectional view of a section of the medication delivery pen shown in Fig. 11.

DETAILED DESCRIPTION OF THE INVENTION

5

A medication delivery pen 10 according to the present invention is shown in Figs. 1-12. Medication delivery pen 10 includes a cap 1 removably attached to a cartridge holder 2 so to cover cartridge holder 2 between uses of medication delivery pen 10. Cartridge holder 2 receives a cartridge 100, shown in Fig. 9, that is commonly used in such medication delivery pens to provide medication and/or insulin for an injection. Medication delivery pen 10 includes a body 5 having a distal end 51 and a proximal end 52, with cartridge holder 2 being attached to distal end 51 of body 5. Medication delivery pen 10 also includes a dose knob 7, a driver 8, a leadscrew 9, a leadscrew spinner 3, a retract nut 4, a shuttle 6, and a push button 71. Each of these elements are more clearly shown in Figs. 2-8 and are more fully described below.

Driver 8 includes a distal end 81 and a proximal end 82, wherein distal end 81 receives drive nut 8A. In addition, driver 8 includes a plurality of ratchet fingers 84 at distal end 81 that engage a ratchet 53, shown in Fig. 6, within body 5 to allow driver 8 to rotate only in one direction with respect to body 5. Drive nut 8A, shown in Fig. 3, includes a set of threads 85 that interface with a matching set of threads 93 on leadscrew 9, shown in Fig. 2. Leadscrew 9 shown in Fig. 2 includes a distal end 91 and a proximal end 92, with proximal end 92 receiving an end cap or co-pilot 9A, shown in Fig. 1, and distal end 91 receiving leadscrew spinner 3 also shown in Fig. 1. Fig. 2 shows a distinctive thread formed by a set of threads 93 on leadscrew 9. Each thread 93 includes distinctive pyramid projection 94 formed by grooves 95 that cut through threads 93 in a longitudinal direction on leadscrew 9.

Fig. 3 shows drive nut 8A which is received in distal end 81 of driver 8. Drive nut 8A is held within distal end 81 of driver 8 by flanges 89 on drive nut 8A. During assembly, drive nut 8A is inserted through distal end 51 of body 5 while driver 8 is inserted through the proximal end 52 of body 5 and snapped together within body 5 to capture a wall 57 within body 5, shown in Fig. 6.

Fig. 4 is a perspective view of retract nut 4 that more clearly shows attachment arms 41 that mate with snap ring 83 on drive nut 8A to rotatably attach retract nut 4. Retract nut 4 also includes an opening 42 therethrough having a plus sign shape that 10 mates with a set of grooves 94 in leadscrew 9, shown in Fig. 2, to prevent leadscrew 9 from rotating with respect to retract nut 4. Retract nut 4 also has a distal toothed surface 45 that mates with teeth 21 on cartridge holder 2 to prevent retract nut 4 and leadscrew 9 from rotating when cartridge holder 2 is mounted on body 5. However, when cartridge holder 2 is not mounted into body 5, retract nut 4 and leadscrew 9 are free to rotate which 15 permits leadscrew 9 to be free to backdrive into body 5 as the user pushes a new cartridge into place. A leadscrew spinner 3 is attached to a distal end 91 of leadscrew 9 and is allowed to spin freely on leadscrew 9, shown in Fig. 2, in relation to a rubber plunger 111 within the cartridge as leadscrew 9 is backdriven into body 5.

Medication delivery pen 10 according to the present invention also includes a spring 99 and a spring cap 98, as shown in Fig. 1. During assembly spring 99 is placed 20 into driver 8 and is held within driver 8 using spring cap 98 that attaches to proximal end 82 of driver 8. Spring 99 is then contained between spring cap 98 and end cap 9A to bias leadscrew in the distal direction to reduce priming of leadscrew 9 with rubber plunger 25 111 and make priming much easier than conventional pens. End cap or co-pilot 9A aids in guiding spring 99 during backdriving to reduce friction or rotation of spring 99. Spring 99, however, is not used to drive leadscrew 9 during medication injection.

When cartridge holder 2 mates with retract nut 4, leadscrew 9 is locked against rotation which then enables threads 85 within drive nut 8A to drive leadscrew 9 in the distal direction towards and against the rubber plunger 111 within cartridge 100 during a dispensing operation. Snap ring 83 on drive nut 8A also allows retract nut 4 to float 5 captive thereon thus trapping it from spinning down leadscrew 9 when exchanging cartridges, should a user invert medication delivery pen 10 when changing cartridges.

Fig. 5 is a perspective view of shuttle 6 showing a plurality of keyways 63 therein that travel within a respective set of keys 86 on driver 8, shown in Fig. 1. Shuttle 6 also 10 includes a distal end 61 and a proximal end 62, proximal end 62 having a plurality of teeth 65 and a plurality of ratchets 64 extending from teeth 65 towards distal end 61. Ratchets 64 engage with a plurality of ratchet fingers 73 on a distal end 71 of dose knob 7, shown in Fig. 7 and discussed further below.

15 Fig. 6 is a cross-sectional view of body 5 more clearly showing distal end 51 and proximal end 52 having a set of dose setting threads 54 therein together with a dose viewing window 55 that receives a magnifier 59 used to magnify the dosage numerals 74 on dose knob 7. Another set of threads 56 located within distal end 51 are used to attach 20 cartridge holder 2 in this embodiment. Of course, other means for attaching cartridge holder 2 to body 5 could also be used and fall within the scope of the present invention as long as sufficient force is applied to retract nut 4 to prevent rotation of retract nut 4 and leadscrew 9 within body 5 when cartridge holder 2 is attached to body 5.

25 Fig. 9 is a cross sectional view of medication delivery pen 10 shown in Fig. 1 fully assembled and in a dose setting condition or a condition for transportability. In Fig. 9 shuttle 6 is fully received within dose knob 7 such that teeth 65 on proximal end 62 of

shuttle 6 are engaged with teeth 78, shown in Fig. 8, within dose knob 7. This causes shuttle 6 and dose knob 7 to rotate together during dose delivery.

Fig. 7 is a perspective view of dose knob 7 having a distal end 71 and a proximal end 72, with a textured section 76 near proximal end 72 to aide the user in turning dose knob 7 to set a desired dose when using medication delivery pen 10. Distal end 71 includes the plurality of ratchet fingers 73 that engage ratchet 64 on shuttle 6 when setting a dose, as shown in Fig. 10, until medication delivery pen 10 is in a reset condition, as shown in Fig. 11. When medication delivery pen 10 is in the reset condition, shuttle 6 has disengaged from dose knob 7 as clearly seen in Figs. 11 and 12. Alternatively, as shown in Fig. 10 during a dose setting condition, shuttle 6 is within dose knob 7 such that ratchet 64 is engaged with ratchet fingers 73. When a user is turning dose knob 7, shuttle 6 slides along driver 8 towards proximal end 52 of body 5 and dose knob 7 rotates around shuttle 6 causing ratchet fingers 73 on dose knob 7 to engage and disengage with ratchet 64 on shuttle 6 to provide an audible and tactile signal during dose setting. As shuttle 6 slides along driver 8, keyways 63 within shuttle 6 interact with keys 86 on driver 8. After a desired dose has been set by the user using dose knob 7, movement of dose knob 7 in a distal direction will cause shuttle 6 to rotate due to the interaction between teeth 65 on proximal end 62 of shuttle 6 and teeth 78 within dose knob 7. As shuttle 6 rotates, keyways 63 within shuttle 6 interact with keys 86 on driver 8 to rotate drive nut 8A about leadscrew 9 and move leadscrew 9 in a distal direction to dispense medication from cartridge 100.

The user sets a desired dose by rotating dose knob 7 in a clockwise direction until the desired dose is displayed through magnifier 59 in body 5. Dose knob 7 includes a plurality of dosage numerals 74 that show through window 55 and an indicator 75, i.e., ▲, that identifies a "reset condition" for medication delivery pen 10. When the desired

dose is reached, the user depresses a push button 71 attached to proximal end 72 of dose knob 7 until dose knob 7 has fully returned within body 5 to the dose setting position shown in Fig. 9.

5 A significant function of the drive mechanism within medication delivery pen 10 is that if the user overshoots the desired dose, medication delivery pen 10 can be reset so that the user may redial for the desired dose. This is accomplished by rotating dose knob 7 completely past the maximum value (30 or 60) until indicator 75 on dose knob 7 is displayed in through magnifier 59 within body 5. This disengages ratchet fingers 73
10 within dose knob 7 from ratchet 64 on shuttle 6 by forcing them apart and releasing shuttle 6 from within dose knob 7. This action is caused by proximal end 62 engaging with a set of stops 87, shown in Fig. 1, on driver 8. Dose knob 7 is then free to rotate back to an initial dose position ("0") upon which ratchet fingers 73 are forced to reengage
15 with ratchet 64 on shuttle 6. Disengaging and re-engaging ratchet 64 and ratchet fingers 73 requires significant tactile manipulation and results in an audible click which alerts the user that the resetting function has been performed. After performing the resetting function, ratchet 64 and ratchet fingers 73 are no longer engaged so that no audible or tactile feedback is generated during rotation of dose knob 7 until reset function is completed.

20

While the present invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims.

What is claimed is:

1. A medication delivery pen comprising:
 - a body having opposing proximal and distal ends;
 - a dose control mechanism disposed in the proximal end of the body for setting and administering a dosage of medication;
 - 5 a cartridge holder having a cartridge with a pierceably sealed distal end, an open proximal end removably attachable to the distal end of the body, and a plunger in sliding, fluid tight engagement within said cartridge;
 - a drive mechanism coupled between the dose control mechanism and the cartridge
 - 10 to exert an axial force on the plunger to inject the set dosage of medication, wherein the dose control mechanism triggers the drive mechanism to administer the injection of medication held in the cartridge; and
 - 15 a mechanism that automatically disengages the drive mechanism from the dose control mechanism to permit the user to reset the dosage on the medication delivery pen.
2. The medication delivery pen of claim 1 further comprising an automatic mechanism that allows the user to easily load a new cartridge and automatically reposition the drive mechanism on the plunger when the cartridge holder is mounted on the body of the medication delivery pen.
 - 20
3. The medication delivery pen of claim 1 further comprising a magnifier on the body for viewing and setting of the desired dosage using the dose control mechanism.

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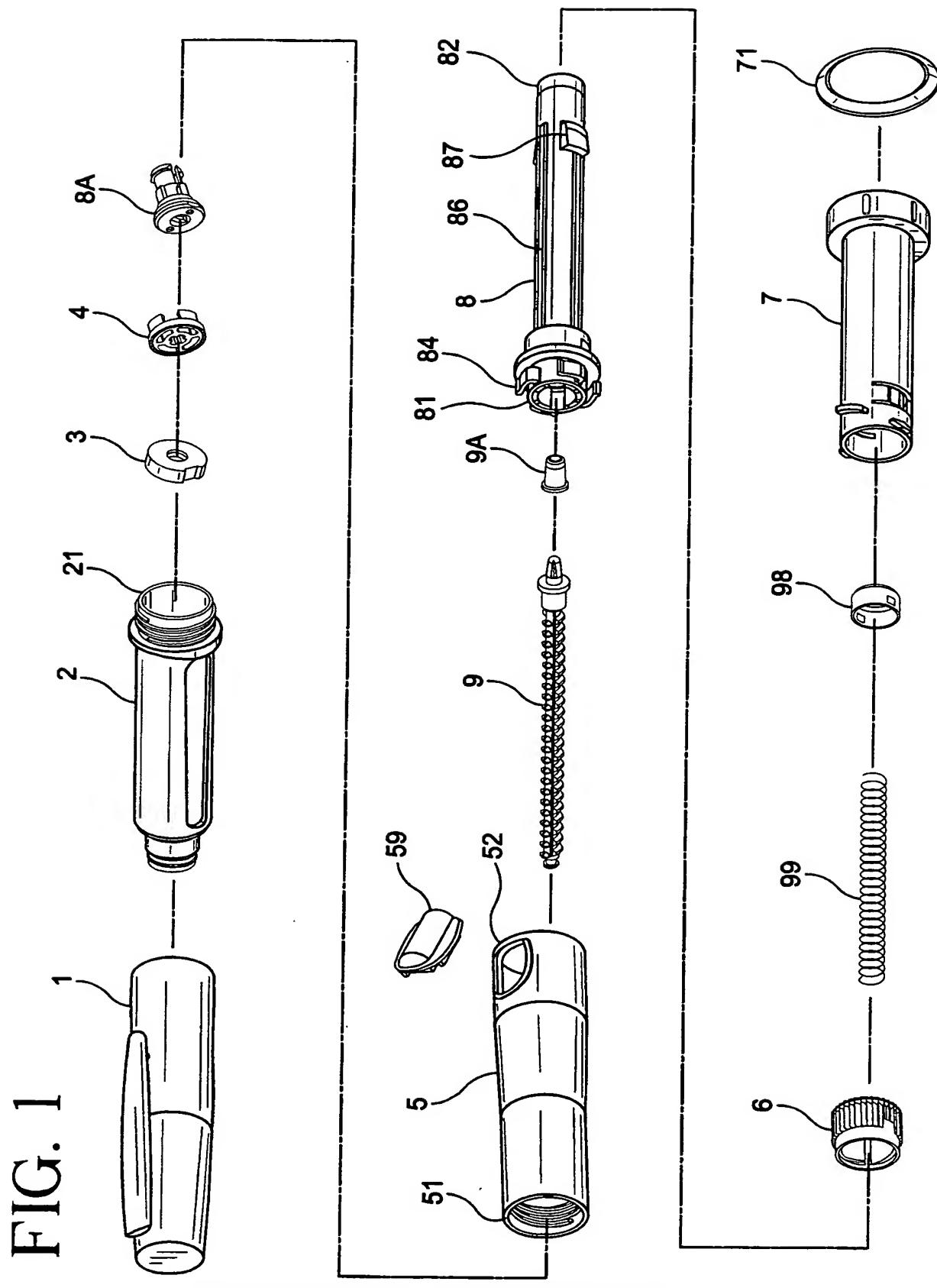


FIG. 1

SUBSTITUTE SHEET (RULE 26)

2/8

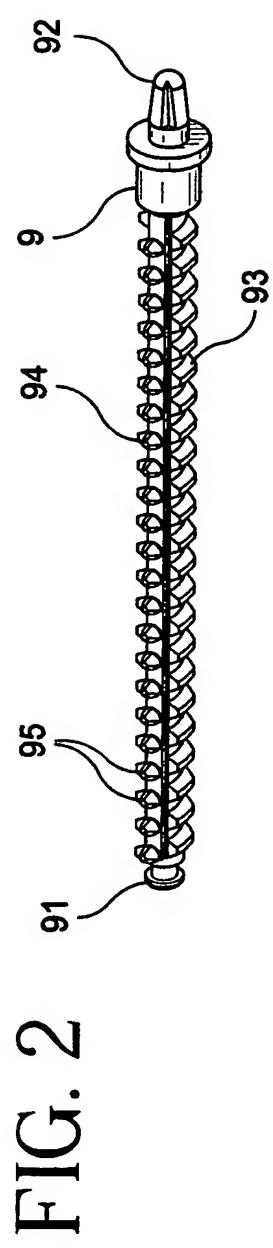


FIG-3

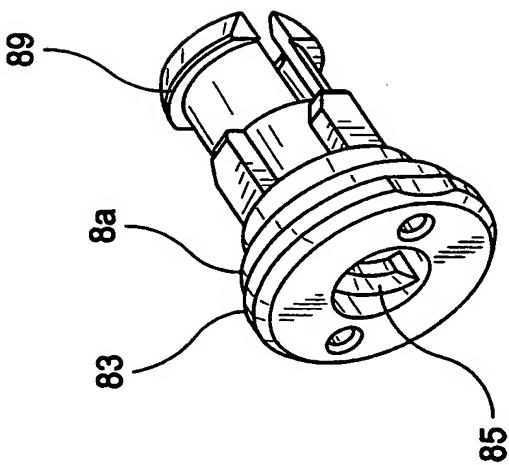
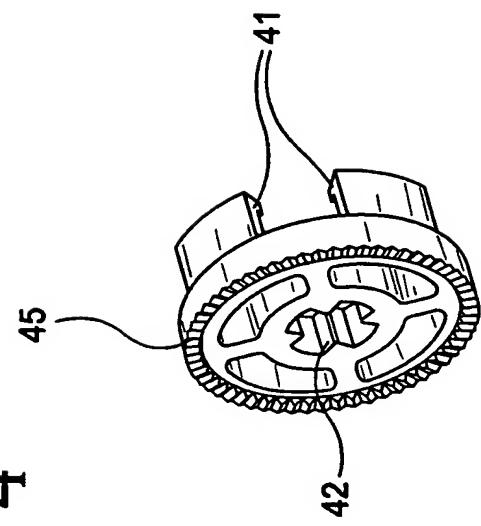


FIG-4



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FIG. 5

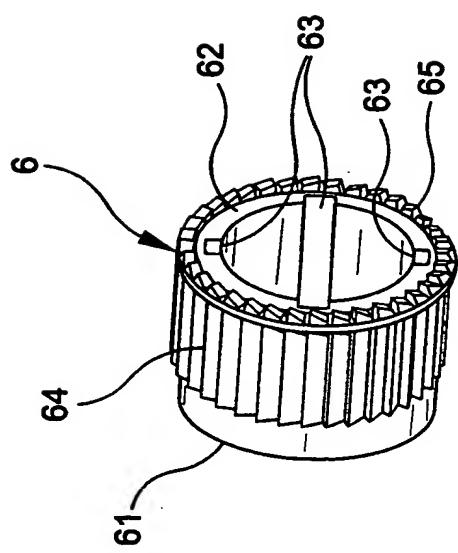
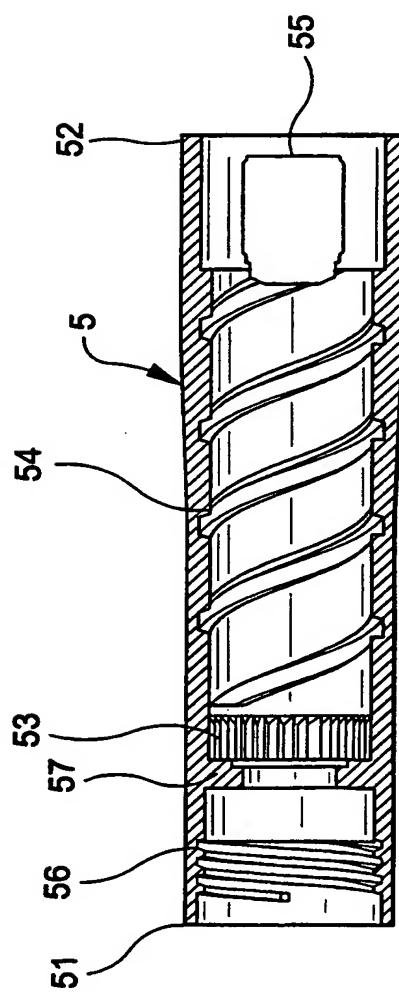


FIG. 6



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FIG. 7

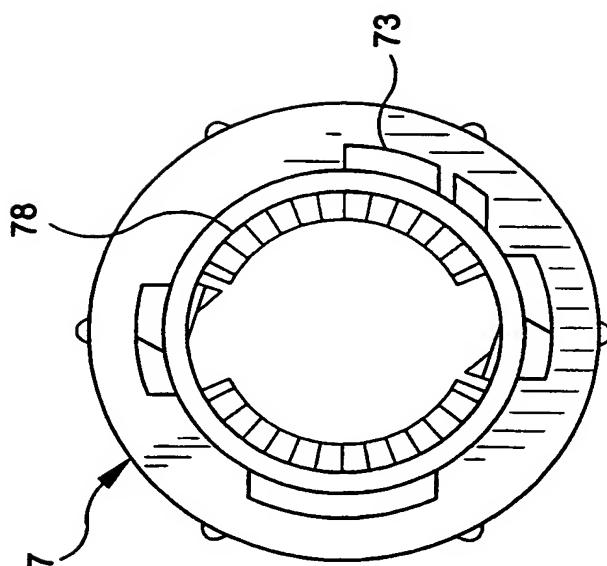
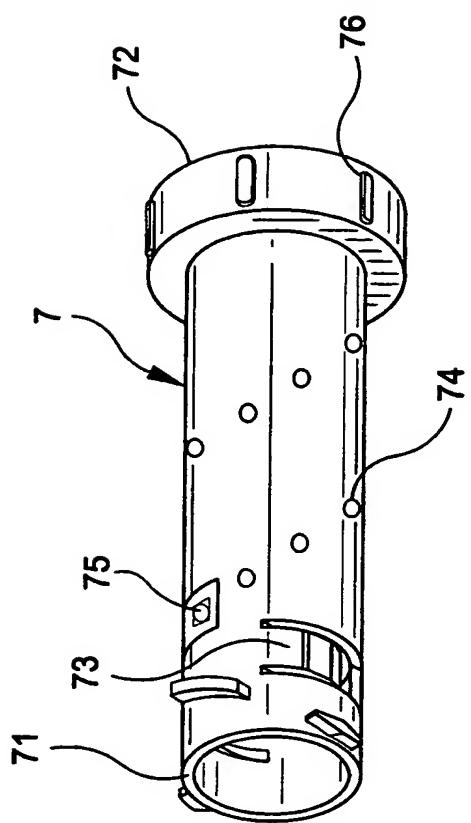


FIG. 8

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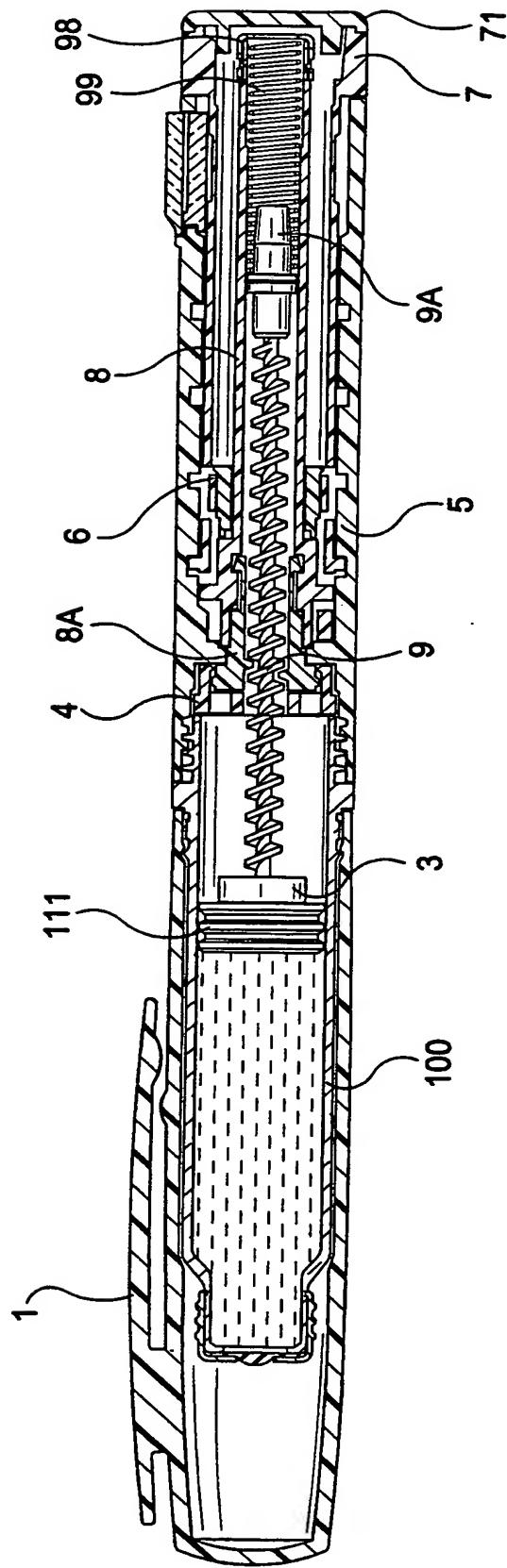


FIG-9

S U B S T I T U T E S H E E T (R U L E 26)

6/8

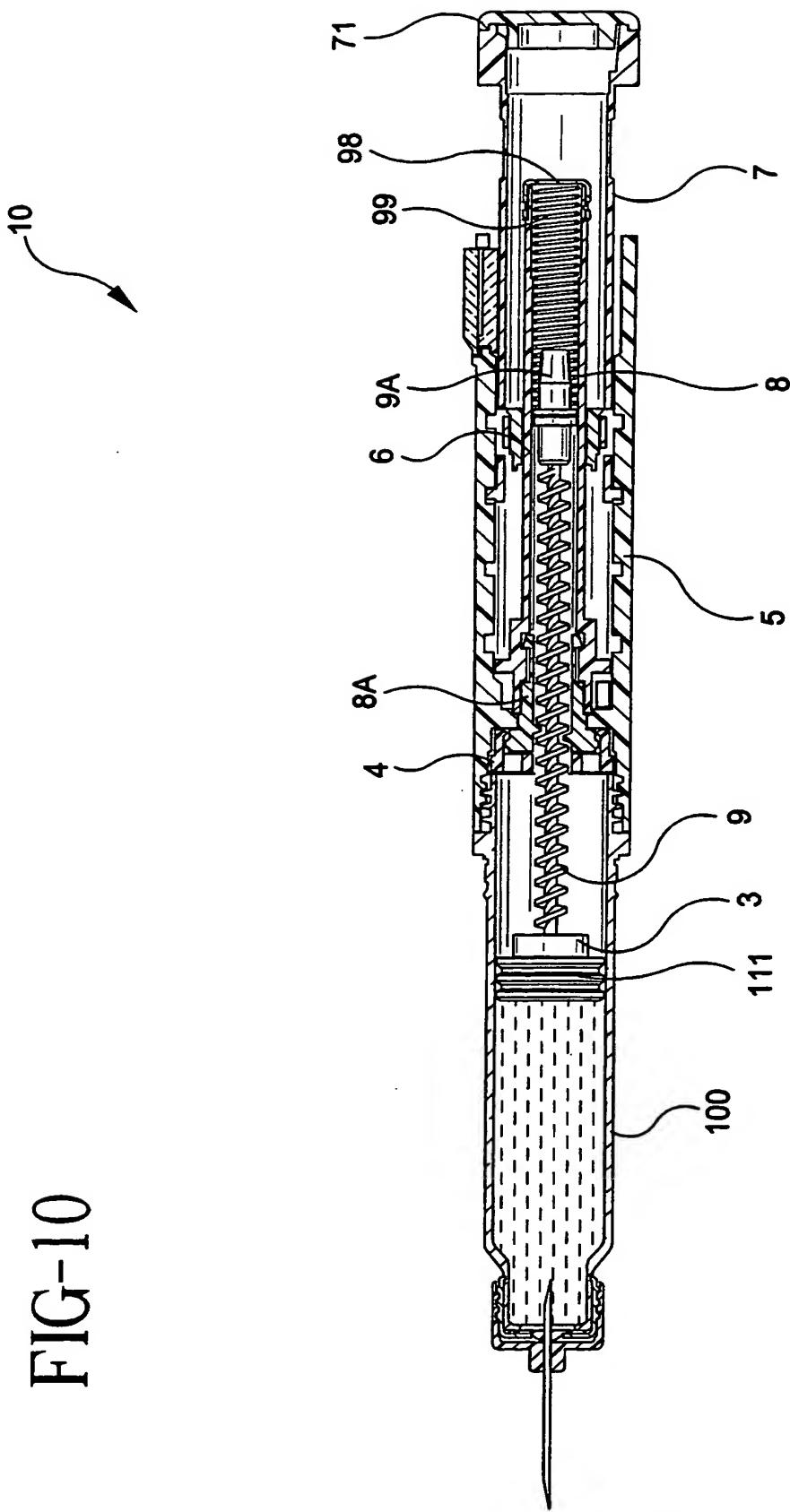


FIG-10

SUBSTITUTE SHEET (RULE 26)

7/8

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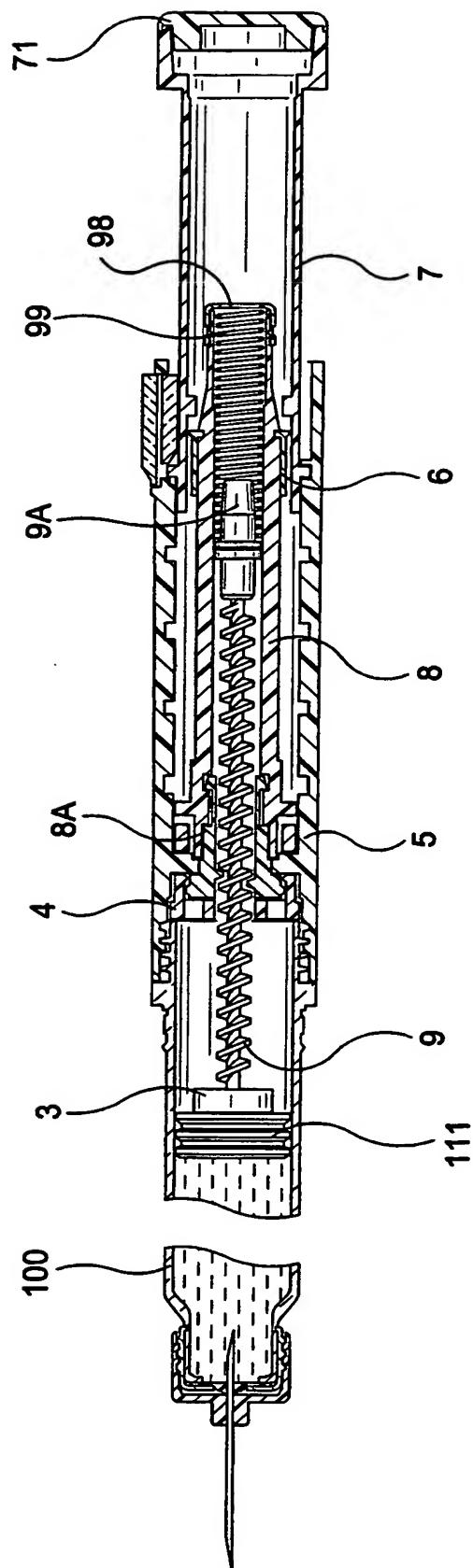


FIG-11

8/8

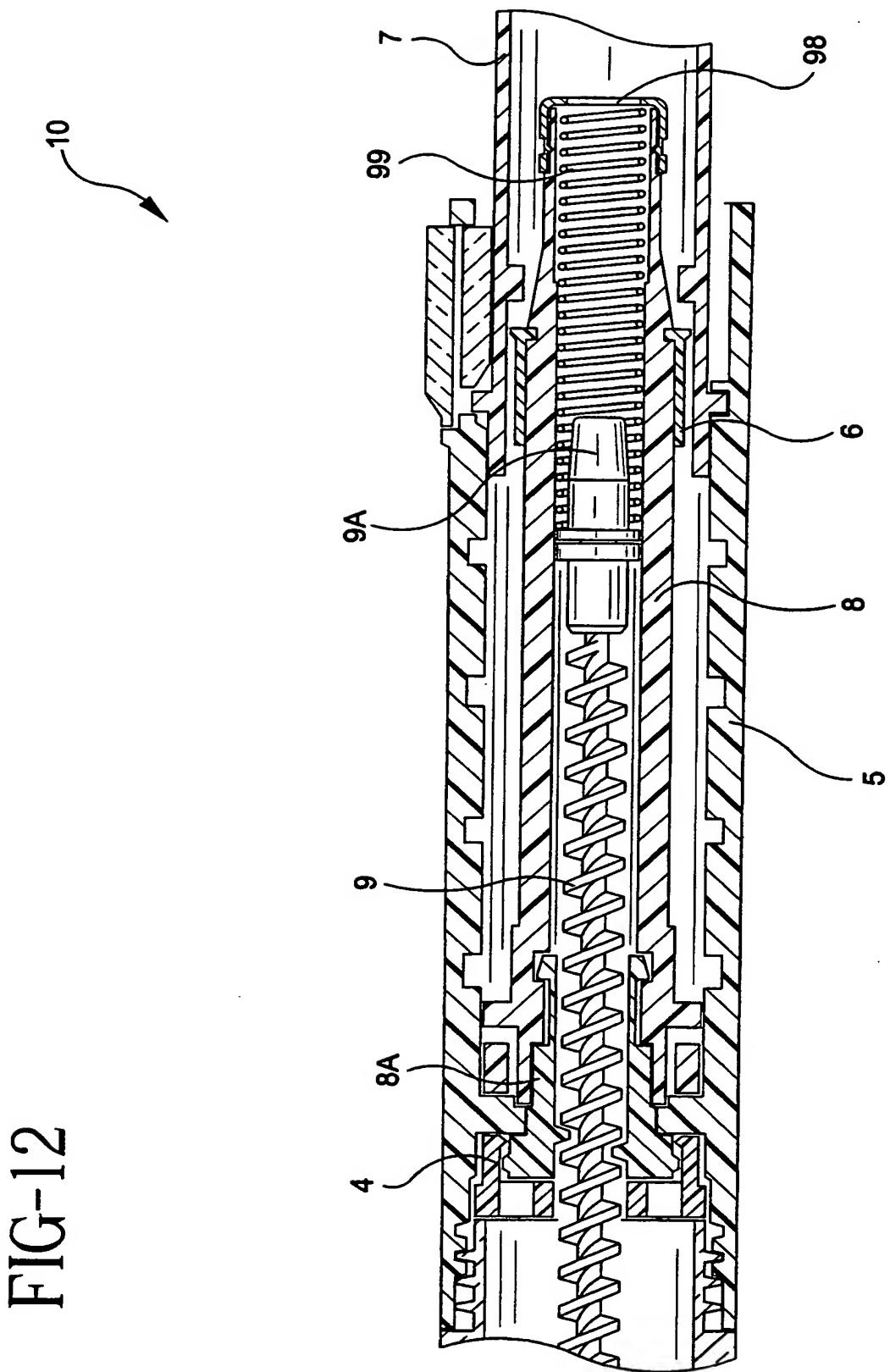


FIG-12

INTERNATIONAL SEARCH REPORT

International application No. PCT/US00/20938

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/00
US CL : 604/181

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,921,966 A (BENDEK et al) 13 July 1999, Fig. 5a.	1-3

Further documents are listed in the continuation of Box C. See patent family annex.

- Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance		
E earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
O document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 OCTOBER 2000	Date of mailing of the international search report 23 OCT 2000
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Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Faxsimile No. (703) 305-3230

Authorized officer

KEVIN C. SIRMONS

Telephone No. (703) 306-5410

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:
USPTO
Assistant Commissioner for Patents
Box PCT
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE
VIA TELEFAX in advance on 15-03-2001
to 001-703-305 3230

Date of mailing (day/month/year)	20.03.01
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Applicant's or agent's file reference P-4615-70	REPLY DUE See paragraph 1 below
International application No. PCT/US 00/ 20938	International filing date (day/month/year) 31/07/2000

Applicant BECTON, DICKINSON AND COMPANY et al.
--

1. REPLY DUE within _____, months/days from the above date of mailing
 NO REPLY DUE

2. COMMUNICATION:

The demand for the above-mentioned application (together with any accompanying papers) and Form PCT/IPEA/436 are transmitted herewith.

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Stephen Moran tel.: (089) 2399/8123 Munich
--	---



The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line
IPEA/ EP

PCT

EPO - Munich
22

CHAPTER II

DEMAND

26 Feb. 2001

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND 26/02/01
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		
International application No. PCT/US00/20938	International filing date (day/month/year) 31 July 2000 (31.07.00)	(Earliest) Priority date (day/month/year) 05 August 1999 (05.08.99)
Title of invention MEDICATION DELIVERY PEN		
Box No. II APPLICANT(S)		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) BECTON, DICKINSON AND COMPANY 1 Becton Drive Franklin Lakes, New Jersey 07417-1880 US		Telephone No.: 201-847-7112
		Facsimile No.: 201-847-5377
		Teleprinter No.:
State (that is, country) of nationality: US	State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) BUSH, JR, CHARLES L. 44 Broadway Lane Fairfield, New Jersey 07004 US		
State (that is, country) of nationality: US	State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) PADDOCK, DOUGLAS 40 Meadow Pond Road Hamburg, New Jersey 07419 US		
State (that is, country) of nationality: US	State (that is, country) of residence: US	
<input checked="" type="checkbox"/> Further applicants are indicated on a continuation sheet.		

① 3285, 80
Zur Kasse (A)

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is agent common representative
 and has been appointed earlier and represents the applicant(s) also for international preliminary examination.
 is hereby appointed and any earlier appointment of (an) agent(s) /common representative is hereby revoked.
 is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: (*Family name followed by given name; for a legal entity, full official
The address must include postal code and name of country.*)

Fiedler, Alan W.
 Becton, Dickinson and Company
 1 Becton Drive
 Franklin Lakes, New Jersey 07417-1880
 US

Telephone No.:
201-847-7112

Facsimile No.:
201-847-5377

Teleprinter No.:

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

the international application as originally filed.
 the description as originally filed
 as amended under Article 34

the claims as originally filed
 as amended under Article 19 (together with any accompanying statement)
 as amended under Article 34

the drawings as originally filed
 as amended under Article 34

2. The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). (*This check-box may be marked only where the time limit under Article 19 has not yet expired.*)

- * Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

which is the language in which the international application was filed.
 which is the language of a translation furnished for the purposes of international search.
 which is the language of publication of the international application.
 which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States (*that is, all States which have been designated and which are bound by Chapter II of the PCT*)

excluding the following States which the applicant wishes not to elect:

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet is not to be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BURBANK III, JOHN E.

106 Haviland Road

Ridgefield, Connecticut 06877

US

State *(that is, country)* of nationality:

US

State *(that is, country)* of residence:

US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GABEL, JONATHAN B.

7 Beaver Dam Road

Randolph, New Jersey 07869

US

State *(that is, country)* of nationality:

US

State *(that is, country)* of residence:

US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

SHARIFI-MEHR, AMIR ALI

39 Glen Avenue

Millburn, New Jersey 07041

US

State *(that is, country)* of nationality:

US

State *(that is, country)* of residence:

US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

NGUYEN, TUAN V.

Appt. 0-9

475 West End Avenue

North Plainfield, New Jersey 07060

US

State *(that is, country)* of nationality:

US

State *(that is, country)* of residence:

US

Further applicants are indicated on another continuation sheet.

Box N . VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | | |
|---|---|--------|--------------------------|--------------------------|
| 1. translation of international application | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. amendments under Article 34 | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. copy (or where required, translation) of amendments under Article 19 | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. letter | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. other (specify) | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |

For International Preliminary
Examining Authority use only

received not received

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input type="checkbox"/> other (specify): |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Alan W. Fiedler, Esq. / Reg. No. 33,690
Becton, Dickinson and Company
Attorney/Agent for Applicant

For International Preliminary Examining Authority use only**1. Date of actual receipt of DEMAND:****2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):**

3. The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. The applicant has been informed accordingly.
4. The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on: